

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/713,498	ZHAO, CHAOYING	
	<b>Examiner</b>	<b>Art Unit</b>	
	JOHN PAK	1616	

All participants (applicant, applicant's representative, PTO personnel):

(1) JOHN PAK. (3) \_\_\_\_.  
 (2) GREGORY MAYBACK. (4) \_\_\_\_.

Date of Interview: 3/24/05 -see below.

Type: a) Telephonic b) Video Conference  
 c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: All.

Identification of prior art discussed: \_\_\_\_\_.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### **Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### **Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**

#### **Paragraph (b)**

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### **37 CFR §1.2 Business to be transacted in writing.**

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
*(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)*
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

This Interview Summary Record is a summary of several telephone discussions conducted by Examiner Pak and Mr. Mayback in the latter part of March 2005.

On 3/16/2005, the Examiner contacted Mr. Mayback to propose limiting all claims to the elected species (hydroxyethyl starch) as the "second substance," wherein the hydroxyethyl starch has feature of claim 22, i.e. at least 10% of the hydroxyethyl starch has a molecular weight of about 25,00-45,00 atomic mass units. The Examiner proposed cancelling all other claims and all other subject matter, which are not directed to the above noted claim limitations. On 3/17/2005, Mr. Mayback stated that he would need to contact the inventor in China, so he could not give an answer right away. Mr. Mayback indicated that an answer by Monday, 3/21/05 was possible. The Examiner explained that the case would be overdue on his docket as of Monday, 3/21/05, so if an agreement cannot be reached by then a lack of unity (restriction) requirement may have to be issued. The Examiner explained that a new lack of unity requirement is needed in this case because the Examiner had grossly underestimated the level of complexity of this case and the prior art related thereto. Full rationale for the lack of unity would be set forth in an Office action, if necessary. The Examiner stated that he would try to limit the further grouping of the claims to about 2 to 4 additional groups.

On 3/21/2005, Mr. Mayback provided the Examiner with a draft version of claim amendments, which adopted all of the Examiner's suggestions (draft version attached hereto). On 3/21/05 and 3/22/05, the Examiner informed Mr. Mayback that the case could not be completed in time, and he had obtained an extension to complete the case as soon as possible -- also, the Examiner noted a spelling error for "Trig" [sic] in claims 20, 42, 44 and 45. Mr. Mayback stated that he could not authorize an Examiner's amendment to correct that spelling until the inventor is contacted. On 3/22/2005, the Examiner called Mr. Mayback to inquire about the descriptive support for the specific percentages recited in claims 37-39 and 44. The Examiner stated that the specific percentages appear to be New Matter. The Examiner stated that specific percentage features were newly presented and not previously examined, and he was not able to spot the new matter significance until that time. The Examiner requested applicant's assistance in pointing out where in the specification applicant found descriptive support for those specific percentage numbers. On 3/24/05, the Examiner called and left a message with Mr. Mayback's assistant to request further resolution of the remaining issues in this case in view of the overdue status of this application on the Examiner's docket. The Examiner stated that he will have to issue an Office action if he does not hear from Mr. Mayback soon. As of the writing of this Interview Summary Record, which is 3/29/05, the Examiner still had not heard back from Mr. Mayback.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applic. No. : 09/713,498 Confirmation No. 4672  
Applicant : Zhao Chaoying et al.  
Filed : November 15, 2000  
Title : Novel Pharmaceutical Compositions for Treating and Saving and the Method for Preparation Thereof  
Group Art Unit : 1616  
Examiner : John Pak  
  
Docket No. : CSIP-001  
Customer No. : 24131

**Proposed Amendments to the Claims:**

1 through 19 (cancelled).

20 (currently amended). A pharmaceutical composition consisting essentially of:

a first substance comprising sodium chloride in an amount between about 1.5% and 6.9% (w/v);

a second substance comprising ~~at least one of hydroxyethyl starch, dextran, carboxymethyl starch, polyvinyl pyrrolidone (PVP), gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N-2 hydroxypropylacrylamide, ethylene epoxide, polypropylene glycol, pectin, and pentahydroxyethyl starch, wherein said second substance is present in an amount between about 3 and 18 % total (w/v), at least 10% of said second substance having a molecular weight of about 25,000-45,000 atomic mass units;~~

*Attachment  
to  
Interview  
Summary  
Record  
of  
3/24/05*

*11 Pages*

a third substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, and Trig (Hydroxymethyl) arninomethane, wherein said third substance is present in an amount between about 0 and 5.4 % total (w/v); and

an injection comprising at least one of water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, Tris solution, and glucose and sodium chloride solution, wherein said injection is present in an amount between about 75.1 % and 95.5% total (w/v),

wherein the total sodium ion concentration does not exceed an equivalent sodium ion concentration of 6.9 % (w/v) sodium chloride solution.

21 (previously presented). The pharmaceutical composition of Claim 20, wherein:

said first substance comprises sodium chloride in an amount between about 4.0 and about 4.4 g per 100 ml; and

said second substance comprises hydroxyethyl starch in an amount between about 7.0 g and about 8.2 g per 100 ml.

22 (cancelled).

23 (cancelled).

24 (cancelled).

25 (previously presented). A method for preparing the pharmaceutical composition of Claim 20, comprising:

dissolving an amount between about 3 g and 18 g of said second substance in a total of 100 ml of said injection;

adding 1.5 g of said first substance; and

mixing said injection to dissolve said first and second substances therein.

26 (cancelled).

27 (previously presented). The method for preparing the pharmaceutical composition of Claim 20 comprising:

dissolving an amount between about 3 g and 18 g of said second substance in a total of 100 ml of said injection;

adding 1.5 g of said first substance;

adding an amount between 0 and about 5.4 g of said third substance, such that the total sodium ion concentration based on said first, second and third substances does not exceed an equivalent sodium ion concentration in a 6.9 % (w/v) sodium chloride solution; and

mixing said injection to dissolve said first, second, and third substances therein.

28 (previously presented). The pharmaceutical composition of Claim 20, wherein

said first substance comprises sodium chloride in an amount of about 1.5 g;

said second substance comprises hydroxyethyl starch in an amount of about 3 g and dextran in an amount of about 9 g;

said third substance comprises sodium bicarbonate in an amount of about 3.4 g; and

said injection comprises physiological saline.

29 (cancelled).

30 (previously presented). The pharmaceutical composition of  
Claim 20, wherein

said first substance comprises sodium chloride in an amount of  
about 4.2 g;

said second substance comprises hydroxyethyl starch in an  
amount of about 7.6 g; and

said injection comprises water.

31 (cancelled).

32 (cancelled).

33 (cancelled).

34 (cancelled).

35 (cancelled).

36 (cancelled).

37 (previously presented). The pharmaceutical composition  
according to claim 20, wherein said first substance is present

in an amount between approximately 1.5% and approximately 5.0% total (w/v).

38 (previously presented). The pharmaceutical composition according to claim 20, wherein said first substance is present in an amount between approximately 1.5% and approximately 5.1% total (w/v).

39 (previously presented). The pharmaceutical composition according to claim 20, wherein said first substance is present in an amount between approximately 1.5% and approximately 5.2% total (w/v).

40 (previously presented). The pharmaceutical composition according to claim 20, wherein said first substance is present in an amount between approximately 1.5% and approximately 4.4% total (w/v).

41 (previously presented). The pharmaceutical composition according to claim 20, wherein said first substance is present in an amount between approximately 4.0% and approximately 4.4% total (w/v).

42 (currently amended). A pharmaceutical composition consisting essentially of:

a first substance comprising sodium chloride in an amount between about 4.0 and about 4.4 g per 100 ml;

a second substance comprising ~~at least one of~~ hydroxyethyl starch in an amount between about 7.0 g and about 8.2 g per 100 ml, at least 10% of said second substance having a molecular weight of about 25,000-45,000 atomic mass units;

a third substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, and Trig (Hydroxymethyl) arninomethane, wherein said third substance is present in an amount between about 0 and 2.5% total (w/v); and

an injection comprising at least one of water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, Tris solution, and glucose and sodium chloride solution, wherein said injection is present in an amount between about 84.9% and 89.0% total (w/v),

wherein the total sodium ion concentration does not exceed an equivalent sodium ion concentration of 6.9 % (w/v) sodium chloride solution.

43 (currently amended). A pharmaceutical composition consisting essentially of:

a first substance comprising sodium chloride in an amount of about 1.5 g;

a second substance comprising ~~at least one of~~ hydroxyethyl starch in an amount of about 3 g and dextran in an amount of about 9 g, at least 10% of said hydroxyethyl starch having a molecular weight of about 25,000-45,000 atomic mass units;

a third substance comprising at least one of sodium bicarbonate in an amount of about 3.4 g; and

an injection comprising physiological saline, said injection being present in an amount of about 83.1% total (w/v),

wherein the total sodium ion concentration does not exceed an equivalent sodium ion concentration of 6.9 % (w/v) sodium chloride solution and the total volume of the composition is 100 ml.

44 (currently amended). A pharmaceutical composition consisting essentially of:

a first substance comprising sodium chloride in an amount of

about 4.2 g;

a second substance comprising ~~at least one of~~ hydroxyethyl starch in an amount of about 7.6 g, at least 10% of said second substance having a molecular weight of about 25,000-45,000 atomic mass units;

a third substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, and Trig (Hydroxymethyl) arninomethane, wherein said third substance is present in an amount between about 0 and 2.7% total (w/v); and

an injection comprising water, said injection being present in an amount between about 85.5% and 88.2% total (w/v),

wherein the total sodium ion concentration does not exceed an equivalent sodium ion concentration of 6.9 % (w/v) sodium chloride solution.

45 (currently amended). A pharmaceutical composition consisting of:

a first substance comprising sodium chloride in an amount between about 1.5% and 6.9% (w/v);

a second substance comprising at least one of hydroxyethyl starch, dextran, carboxymethyl starch, polyvinyl pyrrolidone (PVP), gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N-2-hydroxypropylacrylamide, ethylene epoxide, polypropylene glycol, pectin, and pentahydroxyethyl starch, wherein said second substance is present in an amount between about 3 and 18 % total (w/v), at least 10% of said second substance having a molecular weight of about 25,000-45,000 atomic mass units;

a third substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, and Trig (Hydroxymethyl) arninomethane, wherein said third substance is present in an amount between about 0 and 5.4 % total (w/v); and

an injection comprising at least one of water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, Tris solution, and glucose and sodium chloride solution, wherein said injection is present in an amount between about 75.1 % and 95.5% total (w/v),

wherein the total sodium ion concentration does not exceed an

equivalent sodium ion concentration of 6.9 % (w/v) sodium chloride solution.

**- End of Attachment -**